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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,308

06/16/2005

Lars Winther

09138.0079

2746

63432 7590 01/21/2010
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EXAMINER

SASAKI, SHOGO

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

01/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,308	Applicant(s) WINTHER ET AL.	
	Examiner Shogo Sasaki	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 33-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 40-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/16/2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/18/06, 6/16/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 33-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/9/2009.
2. The traversal is on the ground(s) that the special technical feature of Group II, ventilation of the interior of the processing apparatus, is shared by Group I. This is not found persuasive because independent claims 1 or 40 do not have to be limited to an apparatus with a ventilation system. Therefore, there exists lack of unity a priori. In addition, even if the feature is shared, claims 1 and 40 are not applicant's contribution over the prior art. There is also lack of unity a posteriori. (See prior art rejections.)

Claim Interpretations

3. Regarding claims 1, 7, 8, 11, 25, 26, 27, 29, 30, 31, 40, 46 47, 50, 64, 65, 66, 67, 68, 69 and 70, recitations [claims 1 and 40] "for automatic processing of at least one biological sample accommodated on a carrier member, such as a slide, by applying a predetermined amount of reagents in a predetermined sequence according to a processing protocol," "for accommodating at least one carrier member for a sample," and "protecting said at least one sample processing section in said housing;" [claims 7 and 46] "such as at least one biological sample accommodated on a carrier in the at least one processing section;" [claims 8 and 47] "arranged for comprising at least one sample on a carrier and/or at least one section arranged for comprising at least one reagent in a container;" [claims 11 and 50] "for data communication with a data processing device, such as a computer, wherein the protocol for the processing of the particular sample is stored, and where from control data are provided to the climate control means;" [claims 25 and 64] "for adapting the inflowing air with predetermined characteristics;" [claims 26 and 65] "to ensure high and uniform humidity in the chamber;" [claims 27 and 66] "controls humidity by spraying water droplets or having a

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water surface;” [claims 28 and 67] “where the recycled air is drawn through filters to remove fumes and filters to adjust the humidity;” [claims 29 and 68] “controls the humidity to never be below a predetermined level, to prevent drying out of the sample;” [claims 30 and 69] “by which disinfectants, UV protectants or other compounds may be added to the inlet air to prevent microbial growth or discolouring;” and [claims 31 and 70] “addition of fluids from the group consisting of reagents, neutral gas, oxygen, carbon dioxide, nitrogen, water droplets, and formamide,” which are directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art.

4. Claims 1 and 40 do not positively set forth “a carrier,” “a processing protocol” and “a climate control means” as part of the claimed subject matter. Any further references to said elements were not given patentable weight even if those references further limit said unclaimed element.

As to the “climate control means,” does applicant intend for the “climate control means” to be a means for receiving the signal from the sensor and sending the signal to the climate control device (a computer/controller); or does applicant intend for the climate control device to be considered same as the climate control means? (See paragraphs 21-23 below.)

5. Regarding claims 1 and 40, the term “section” does not inherently impart any specific structural requirement. It is unclear how such a section can be labeled a “sample processing” portion of the apparatus. The same applies to the section in claims 7, 8, 46 and 47. The element was interpreted to mean a portion of the housing that may be used for processing a sample.

6. Claims 4 and 43 do not positively set forth “an air inlet/outlet manifold,” “a laboratory facility accommodating the apparatus” or “the building accommodating the laboratory” as part of the claimed subject matter.

7. Claims 7 and 46 do not positively set forth “a plurality of sections” as part of the claimed subject matter. Any further references to said elements were not given patentable weight even if those references further limit said unclaimed element.

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8. Claims 9 and 48 do not positively set forth "a carrier" and "a sample processing protocol" as part of the claimed subject matter. Any further references to said elements were not given patentable weight even if those references further limit said unclaimed element.

9. Claims 10 and 49 do not positively set forth "external or internal sensor" as part of the claimed subject matter. Any further references to said elements were not given patentable weight even if those references further limit said unclaimed element.

10. Claims 11 and 50 do not positively set forth "a data processing device" as part of the claimed subject matter. Any further references to said element were not given patentable weight even if those references further limit said unclaimed element.

11. Regarding claims 18 and 57, the characteristics of air flowing into apparatus are not structures, and they do not further structurally limit the apparatus or the opening.

12. Claims 22, 23, 61 and 62 do not positively set forth "an outlet" as part of the claimed subject matter. Any further references to said element were not given patentable weight even if those references further limit said unclaimed element.

13. Claims 32 and 71 do not positively set forth "the sample carrier" or "a carrier rack assembly" as part of the claimed subject matter. Any further references to said elements were not given patentable weight even if those references further limit said unclaimed element.

Claim Objections

14. Claims 40-71 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1-32. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper to object to the other as being a substantial duplicate of the claim.

15. Regarding claims 4-7, 12-16, 19, 22, 22-25, 32, 41-46, 51-55, 58, 63, 64 and 71, the phrases "any of the claims 1," "any of claims 1" or "either one of claim 40" render said claims unclear. The phrases are interpreted mean "claim 1" and "claim 40."

16. Regarding claim 24, it should be "cover is" instead of "cover are."

Drawings

17. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, [claims 1-4, 10, 40-43, and 49] “sensor(s);” [claims 7, 8, 46 and 47] “a plurality of covers” and “a plurality of interior spaces of the apparatus” and [claim 17 and 56] “fan” and “opening” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

18. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Fig. 4 does not clearly show both the ventilation assembly (80) and air manipulation devices (81, 82) described in [0049]. In addition, the figure is mostly blacked out. Furthermore, it is unclear what the element 80 in Figure 4 is showing. Does the ventilation assembly comprise the air manipulation assembly 81 and 82? The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

19. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification lacks antecedent basis for the claimed terminology, “fan in an opening” in claims 17 and 56.

Claim Rejections - 35 USC § 112

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 1-32 and 40-71 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is: a computer/processor/software for controlling the climate control device. It appears that an element such as “data processing device” (See for e.g. [0021]) will have to be claimed as part of the apparatus. According to the specification ([0043]), the climate control (121, 122, 123) are merely a portion of the housing with two openings (ducts), which may be connected to or may further comprise a device such as shown in Fig. 4. How can such a feature receive a signal from the sensor and control temperature, pressure and air quality?

It is suggested to positively claim a controller and process steps for the controller such as: receiving the signal from the sensor; maintaining pressure within the device ([0013]) and etc. For instance, claim 12 merely recites a purpose of an unclaimed process step(s). Regarding claims 1, 9, 12, 13, 15, 40, 48, 51, 52 and 54, proper and conventional phrases to incorporate an active process limitation with patentable weight into an apparatus claim are for e.g., “a controller configured to/for...” and “a controller programmed to/for...” for performing an active process step(s)/scheme(s).

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22. Claims 1-32 and 40-71 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements. See MPEP § 2172.01. The omitted structural elements and their cooperative relationships are: at least a relationship between the housing-cove and the climate control device.

23. Claims 1-32 and 40-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 40 recite the limitation "the climate control means." There is insufficient antecedent basis for this limitation in the claims. Regarding said limitation, it is unclear if applicant intends to invoke the 112(6) language. The proper format is "means for..."

Regarding claims 1, 8, 40 and 47, the term "section" does not inherently impart any specific structural requirement. It is unclear how such a section can be labeled a "sample processing" portion of the apparatus. The phrase "sample processing" merely implies the intended use of the section.

Regarding claims 4, 7, 11, 18, 43, 46, 50 and 57, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Claims 4 and 43 recite the limitation "the building." There is insufficient antecedent basis for this limitation in the claims.

Regarding claims 5 and 44, it is unclear how the cover may be labeled an "openable hood" without reciting structural elements of the cover and the structural relationship between the cover and the housing (See [0041]).

Regarding claims 6 and 45, it is unclear how the element (cover) that defines the invention (apparatus) can be defined as being integral with the apparatus (invention itself). Did applicant mean the cover is integral with the housing?

Regarding claims 10 and 49, it is unclear if applicant intend for the sensor in claims 1 and 40 to be the external and internal sensors. If so, it is unclear how claims 1

and 40 provides proper antecedent basis for the external or internal sensors. It is noted that there are no other sensors recited in claims 1, 10, 40 and 49.

Regarding claims 12, 13, 51 and 52, it is unclear how the control device regulates the pressure without reciting a process for performing so; or reciting structural elements of a computer/controller that enable the process. Claims 12 and 51 merely recites a purpose of an unclaimed process step(s) for the unclaimed computer/controller.

Regarding claims 14 and 53, it is unclear if the controller included a function of humidity control, or it comprises a humidity controller.

Regarding claims 15 and 54, it is unclear how the control device regulates the temperature without reciting a process for performing so; or reciting structural elements of the controller that enable the process. Claims 15 and 54 merely recites a purpose of an unclaimed process step(s) for the unclaimed computer/controller.

Regarding claims 16 and 55, it is unclear how a ventilation system "automatically" exchanges the air in the interior space without reciting a specific structure of the system. It is unclear how the system may be labeled a "ventilation system" and how such system is capable of ventilating the apparatus.

Regarding claims 17 and 56, it is unclear where said opening is located in the apparatus, and if applicant intends for the opening to be an element of the invention.

Regarding claims 18, 25, 57 and 64, it is unclear how a device may be labeled an "air manipulation device" without reciting structural elements of the device that enable said device to manipulate air.

Regarding claims 19 and 58, it is unclear how a device may be labeled an "exhaustion device" without reciting structural elements of the device that set forth its capability of removing fumes from the interior space.

Regarding claims 20 and 59, it is unclear how: (a) a device is capable of recycling air for humidity, temperature and toxic control; (b) a device is capable of removing toxic elements from the air to be recycled; and (c) a device is capable of supplying humidity to the air to be recycled and/or a heater/cooling device capable of controlling the temperature of the air to be recycled. It is also unclear where said

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devices are located in the apparatus. The claims recite variety of process limitations "capable of..." However there are no structural elements claimed in said claims that enable such performances. The devices cannot be structurally limited by their intended use/effect. The structural relationships between said devices and the controller must also be positively claimed. It appears that the controller is configured to control said devices, therefore the recitation establishing the relationships, such as said controller sending the signal/instruction to such devices will have to be claimed.

Regarding multiple and/or in claim 20 and 59, alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C. Other form "wherein R is A, B, C or D" shall also be considered proper. See MPEP 2173.059 (h).

Claims 22, 23, 61 and 62 recite the limitations "the level" and "the at least one slide." There is insufficient antecedent basis for this limitation in the claims.

Regarding claims 25 and 64, the phrase "inlet means for..." must not be modified by sufficient structure for achieving the specified function. (USC 112(6)) It is unclear if it is the inlet means that adapts the inflowing air with predetermined characteristics; or it is the air manipulation device that adapts the inflowing air with predetermined characteristics.

Regarding claims 26 and 65, it is unclear if "a humid filter" is a moist filter, or it is a filter that is designed to filter out moisture.

Regarding claims 28 and 67, it is unclear how a device may be labeled an "air recycling device" without reciting structural elements of the device.

Regarding claims 30, 31, 69 and 70, it is unclear how a device may be labeled an "air additive supply device" or "air supply" capable of supply additives into the apparatus without reciting structural elements of the device.

Regarding claims 32 and 71, it is not clear if "at least one sensor" is the same sensor recited in claims 1 and 40 or some other sensor.

Claims 32 and 71 recites the limitation "the sample carrier." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25. Claims 1, 2, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated Orimo (US 4338279).

Regarding claims 1, 2, 40 and 41, Orimo discloses (Fig. 3, 4 and 5; and C7/L15-C8/L33) an automatic analyzing apparatus comprising a housing frame (25); at least one sample processing section, said at least one sample processing section is provided within said housing (39, 40); a cover, said cover enclosing the sample processing section and defining an interior space between the housing and the cover (26); at least one climate control device configured to control the environment within said interior space (C14/L19-44); and a temperature sensor device capable of providing feedback signals to the climate control means (C14/L19-44).

26. Claims 1-32 and 40-71 are rejected under 35 U.S.C. 102(b) as being anticipated by a human accommodating building in developed countries (such as a building including a science laboratory).

The claims are interpreted in light of the specification. The specification states in paragraph [0052]:

The discussion included in this application is intended to serve as a basic description. The reader should be aware that the specific discussion may not explicitly describe all embodiments possible; many alternatives are implicit. It also may not fully explain the generic nature of the invention and may not explicitly show how each feature

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or element can actually be representative of a broader function or of a great variety of alternative or equivalent elements. Again, these are implicitly included in this disclosure. Where the invention is described in device-oriented terminology, each element of the device implicitly performs a function. Importantly, neither the description nor the terminology is intended to limit the scope of the claims which may be included at any time.

It is noted that there are no specific structures disclosed for the ventilation, air manipulation, exhaustion and pressure control devices. The disclosure only discloses that the apparatus may be connected to devices that are capable of ventilating, controlling pressure, and manipulating air.

Regarding claims 1-32 and 40-71, a human accommodating building comprises:

- a housing frame;
- at least one sample processing section, said at least one sample processing section is provided within said housing (kitchens, refrigerators or laboratories);
- a cover, said cover enclosing the sample processing section and defining an interior space between the housing and the cover (door to the kitchens, refrigerators or laboratories);
- at least one climate control device configured to control the environment within said interior space (an air conditioning (AC) unit or a sprinkler system, for instance);
- a sensor device capable of providing feedback signals to the climate control means (a thermostat and etc);
- wherein the sensor device is a temperature, a pressure, a humidity, an airspeed, or a fume sensor (sensors associated with the AC unit and/or a fire alarm connected the sprinkler system);
- wherein the sensor device comprises internal sensors located inside the interior space (sensors associated with the AC unit and/or the fire alarm);

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- wherein the sensor device comprises external sensors located outside the interior space (a sensor device that detect outside condition to maintain inside condition according to the outside condition such as an energy saver);
- wherein the cover comprises at least one openable (door is openable);
- wherein the cover is an integrated part of the apparatus;
- wherein the cover comprises a plurality of covers (buildings have multiple doors);
- wherein a plurality of interior spaces of the apparatus is defined by said plurality of covers, each interior space including at least one section (rooms);
- wherein the at least one climate control device is arranged to control the climate in each interior space, comprising at least one sample on a carrier, according to a sample processing protocol defined for that particular sample (most rooms are provided with thermostats to control the climate in the rooms);
- wherein the at least one climate control device receives input signals from internal and/or external sensors, and is arranged to adjust the controlling the climate in each interior space, according to the input signals (thermostat, pressure sensor associated with the AC);
- wherein the at least one climate control device includes humidity control within the interior space (The AC does cool the building by taking air's humidity; or a sprinkler on ceiling for extinguishing the fire.);
- wherein the climate control device comprises a ventilation system (the AC);
- wherein the ventilation system comprise a fan in an opening (the AC unit on the roof comprises fans);
- further comprising at least one air manipulation device (the AC);
- wherein the climate control device comprises an exhaustion device capable of removing fumes from the interior space (fans/blowers associated with the AC or a fan for moving air in the building);
- wherein the climate control device comprises a heater/cooling device capable of controlling the temperature of the air to be recycled (the AC);

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- wherein the device configured to recycle air comprises a filter capable of cleaning the air (all AC has filters.);
- wherein said cover is provided with at least one seal element (The refrigerator doors are normally equipped with a gasket. The door to the laboratory/kitchen may be equipped with sealing element. For energy savings or order leaking prevention.);
- wherein an inlet comprising at least one air inlet opening in the housing frame, and wherein an air manipulation device are provided in said inlet means (the AC unit on the roof; or the sprinkler system for extinguishing hot air, i.e. fire.);
- wherein said air manipulation device comprises an a humid filter device (the ACs with a humidifier are common);
- wherein the air manipulation device comprises an air recycling device (the AC);
- wherein the air manipulation device comprises an air additive supply device (Freon in the AC units; aroma therapy; or the hospitals have air sanitizers.);
- the air manipulation device comprises an air additive supply (Freon); and
- wherein the apparatus comprises at least one sensor device, said sensors being arranged in the vicinity of the cover means and/or in the vicinity of the sample carriers on a carrier rack assembly (the fire alarm or the thermostat may be provided by the door.).

Conclusion

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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SS

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/Brian R Gordon/

Primary Examiner, Art Unit 1797